REMARKS

1. Rejection of Claims 43, 45, 50, 52 and 53 under 35 U.S.C. 112, first paragraph.

Claims 43, 45, 50, 52 and 53 were rejected under 35 U.S.C. 112, first paragraph as set forth in the Office Action. In order to expedite allowance of claims, Applicants have, without prejudice or disclaimer of the subject matter thereof, amended Claims 43 and 52 as suggested by the Examiner to recite an antibody that selectively binds to a protein consisting of a specified SEQ ID NO.

In view of the foregoing, Applicants respectfully request withdrawal of the Examiner's rejection of Claims 43, 45, 50, 52 and 53 under 35 U.S.C. 112, first paragraph.

2. Rejection of Claims 43, 45, 50, 52, 53 and 56 under 35 U.S.C. 112, first paragraph.

Claims 43, 45, 50, 52, 53 and 56 were rejected under 35 U.S.C. 112, first paragraph as set forth in the Office Action. Applicants note that Claim 56 has been cancelled.

Applicants traverse the Examiner's rejection. Initially, Applicants note that the amendment of Claims 43 and 52 from "comprising" to "consisting of" language considerably narrows the scope of the claim, which is the eighth factor cited by the Examiner in his undue experimentation analysis. Applicants respectfully argue that techniques for the production of the claimed monoclonal antibody were well known to those of skill in the art at the time of the invention, including knowledge regarding which techniques carry the highest likelihood of success for a given type of protein. That is, Applicants contend that given the disclosure of protein sequence and expression information found in the present specification through working examples, one of skill in the art would not need additional guidance to produce the claimed monoclonal antibody. It has been established "... that a specification need not disclose what is well known in the art." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.* 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986).

In re Wands, 8 *USPQ2d* 1400 (Fed. Cir. 1988) is the leading Federal Circuit decision applying the undue experimentation standard to a biotechnology patent application. Similar to the present case, one claim at issue in *Wands* was to "monoclonal high affinity IgM antibodies" wherein the characterization of the antibodies was primarily via binding affinity constant (not by structure). In the appeal, the PTO agreed that the starting materials and methods to obtain the antibodies were

well-known, but argued that undue experimentation would be required to produce the antibody. The Federal Circuit disagreed and held that the claim was enabled, saying, "the test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine..." 8 USPQ2d at 1404, quoting *Ex parte Jackson*, 217 *USPQ* 805, 807 (Bd. App. 1982). Applicants contend that any experimentation necessary to produce a monoclonal antibody is merely routine in view of the disclosure of the protein structure and the well known techniques for production of monoclonal antibodies available at the time of the invention, and therefore, a rejection on the basis of lack of enablement is improper.

In view of the foregoing, Applicants respectfully request withdrawal of the Examiner=s rejection of Claims 43, 45, 50, 52, 53 and 56 under 35 U.S.C. 112, first paragraph.

3. Rejection of Claims 55 and 57-59 under 35 U.S.C. 103(a).

Claims 55 and 57-59 were rejected under 35 U.S.C. 103(a) as obvious over Tulloch et al. as set forth in the Office Action. In order to expedite allowance of claims, Applicants have cancelled claims 55 and 57-59, therefore rendering the rejection moot.

In view of the foregoing, Applicants respectfully request withdrawal of the Examiner=s rejection of Claims 55 and 57-59 under 35 U.S.C. 103(a).

In view of the foregoing, Applicants respectfully assert that all pending claims are in a condition for allowance. In the event that the Examiner has any questions regarding Applicants; position, the Examiner is invited to contact the below-named representative.

Respectfully submitted,

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